

UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

STEVEN BENGELSDORF, MD, PLLC,	)	
et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	NO. 3:09-0911
	)	Judge Nixon/Bryant
LUMENIS, INC.,	)	<b>Jury Demand</b>
	)	
Defendant.	)	

**MEMORANDUM AND ORDER**

Plaintiffs have filed their Motion To Compel Responses to Interrogatories and Requests for Production of Documents (Docket Entry No. 24), to which defendant responded in opposition (Docket Entry No. 26).

Plaintiffs thereafter filed their "Motion for Leave To File Reply in Support of Motion To Compel and for Leave To Amend Complaint, If Necessary" (Docket Entry No. 30). The Court granted plaintiffs leave to file a reply in support of their motion to compel (Docket Entry No. 33).

Plaintiffs filed a motion for a hearing on their motion to compel responses (Docket Entry No. 31).

Defendant filed a response in opposition to plaintiffs' motion for leave to amend, if necessary (Docket Entry No. 58).

For the reasons stated below, the undersigned Magistrate Judge grants in part and denies in part plaintiffs' motion to compel responses (Docket Entry No. 24), denies without prejudice plaintiffs' motion for leave to amend complaint, if necessary

(Docket Entry No. 30), and denies plaintiffs' motion for hearing (Docket Entry No. 33).

Plaintiffs' motion to compel responses. Plaintiffs seek an order compelling defendant Lumenis to serve "full and complete responses" to four interrogatories served jointly with companion requests for production: numbers 11, 12, 13 and 15. Lumenis has previously served objections that plaintiffs insist lack merit and responses that plaintiffs characterize as insufficient.

Rule 26(b)(1) of the Federal Rules of Civil Procedure permits discovery of "any nonprivileged matter that is relevant to any party's claim or defense." Relevance for discovery purposes is construed broadly. Discoverable evidence need not be admissible at trial; rather, information is discoverable if it is "reasonably calculated to lead to the discovery of admissible evidence." Fed.R.Civ.P. 26(b)(1). Nevertheless, discovery does have "ultimate and necessary boundaries," Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351 (1978), "and it is well established that the scope of discovery is within the sound discretion of the trial court." Coleman v. Am. Red Cross, 23 F.3d 1091, 1096 (6<sup>th</sup> Cir. 1994).

Interrogatory No. 11/Request for Production No. 11: Please describe any consumer reports or any other reports regarding the Lumenis One, including complaints, malfunctions, patient injury, recalls, and any alerts or other reports from any governmental agency, department or administration, including but not limited to the Food and Drug Administration.

Response No. 11: Objection. This interrogatory seeks information that is irrelevant and unlikely to lead to the discovery of admissible evidence. It seeks information that is

confidential, private, proprietary and/or trade secret. It seeks information protected by HIPPA. Notwithstanding and subject to these objections, Lumenis responds as follows: The information requested is publicly available from the FDA's Manufacturer and User Facility Device Experience data base.

Defendant Lumenis objects to this interrogatory and document request primarily on grounds of relevance. Specifically, defendant argues that the scope of this interrogatory and document request exceeds that which is reasonably relevant to any of the claims raised in the complaint. Summarizing, the complaint alleges that plaintiff Bengelsdorf, a physician, purchased a Lumenis One device from the defendant in August 2006. Plaintiffs assert that the Lumenis One device consists of three different modules that can be used to perform many treatments, including photo rejuvenation, laser hair removal, and laser vein removal. In addition, the Lumenis One includes an integrated patient data base used by the operator for storing and tracking patient treatment information, such as dates, device settings, and duration of treatments for individual patients.

The complaint alleges that since purchasing the Lumenis One plaintiffs have experienced "continuous problems with the machine, including numerous error messages and, at times, a system shutdown in the middle of patient treatment." Due to ongoing problems and numerous service visits required to keep the machine operational, plaintiffs allege that upon expiration of the warranty plaintiff Center entered into a Service Contract Agreement with

Lumenis on April 1, 2009. Pursuant to this contract, defendant Lumenis agreed to provide service on the Lumenis One for a period of one year.

After plaintiffs experienced ongoing problems, described as "error messages and complete failure of the machine during patient treatments," a Lumenis service technician informed plaintiffs that the Lumenis One needed a software update. This software update was attempted on May 5, 2009. The complaint alleges that, during the course of this supposed software update, Lumenis technicians negligently deleted all of the data from the patient database on the Lumenis One. Thereafter, the complaint alleges, the Lumenis technicians requested plaintiffs' data backup, purportedly to perform a software update on the backup. Actually, the technicians intended to use the backup to restore the data that they had negligently deleted from plaintiffs' device. However, the complaint alleges that Lumenis technicians then negligently deleted the patient data from plaintiffs' backup database as well. Subsequent efforts to restore the lost data have been unsuccessful.

The complaint contains six numbered counts: (1) breach of the Service Contract Agreement by failing to cure the ongoing problems with the Lumenis One and deletion of data from the Lumenis One database and its backup; (2) negligence in failing to provide service on the Lumenis One and in deleting the patient treatment data previously described; (3) gross negligence in "the deletion of

the backup key for the Lumenis One database and the failure to cure the ongoing problems with the Lumenis One"; (4) fraudulent misrepresentation in failing to disclose that the Lumenis One's database had been deleted during the software update; (5) misrepresentation by concealment by failing to disclose that the Lumenis technicians had deleted the patient database when they requested access to the plaintiffs' backup key; and (6) violation of the Tennessee Consumer Protection Act by "misrepresenting and failing to inform Plaintiffs of the deletion of the database on the Lumenis One and requesting Plaintiffs' backup key, resulting in the deletion of almost three years of patient treatment data."

Given the foregoing allegations, the undersigned Magistrate Judge finds that plaintiffs' motion to compel with respect to interrogatory and request for production No. 11 should be **GRANTED** in part and **DENIED** in part. The Court finds that defendant Lumenis should produce any reports or notices from consumers, customers, governmental agencies or any other source related to excessive error messages, system shutdowns or other interruptions in patient treatment on the Lumenis One device, whether attributable to software problems, switching modules, or any other cause. To the extent that plaintiffs' interrogatory and request for production seeks information about "patient injury, recalls, or other types of malfunctions," the Court finds that such matters are not relevant to claims raised by the plaintiffs in this

action and, to that extent, plaintiffs' motion to compel should be denied.

Interrogatory and Request for Production Nos. 12 and 13:

Interrogatory and Request Nos. 12 and 13 seek information regarding two Lumenis products other than the Lumenis One. These requests and the defendant's responses read as follows:

Interrogatory and Request No. 12: Please describe the M22 Lumenis device and specifically, how it is different from the Lumenis One.

Response No. 12: Objection. This interrogatory seeks information that is irrelevant and unlikely to lead to the discovery of admissible evidence. It seeks information that is confidential, proprietary, and/or trade secret. Notwithstanding and subject to these objections, Lumenis responds as follows: See response to Request for Production No. 12.

Supplemental Response No. 12: The Lumenis One offers Universal IPL, LightSheer Diode Laser, and an Nd:Yag laser. The M22 does not offer the LightSheer capability.

Interrogatory and Request No. 13: Please describe the Lumenis DUET device and specifically, whether there have been any reported problems with its software.

Response No. 13: Objection. This interrogatory seeks information that is irrelevant and unlikely to lead to the discovery of admissible evidence. It seeks information that is confidential, proprietary, and/or trade secret. Notwithstanding and subject to these objections, Lumenis responds as follows: See response to Request for Production No. 13.

Supplemental Response: The Lumenis Duet consists of two LightSheer heads, a LightSheer ET and LightSheer HS.

Plaintiffs argue that defendant's objections lack merit and that its responses are insufficient. Specifically, plaintiffs maintain that the Lumenis response "does not describe all of the

component hardware and software of the M22 Lumenis device or all of the differences between the M22 device and the Lumenis One." Plaintiffs argue that the M22 device was designed and released as the "next generation" Lumenis One device, and was originally named the "Lumenis Two." Plaintiffs maintain that release of the M22 device was necessitated because of Lumenis's recognition of deficiencies in the Lumenis One.

Similarly, plaintiffs argue that "[i]t is likely Lumenis designed the Lumenis DUET device in an attempt to eliminate known problems with the Lumenis One by eliminating or changing problematic elements of that device." Based upon this assertion, plaintiffs argue that information regarding the design and operation of the Lumenis DUET device is relevant to claims raised in this case.

In opposition to plaintiffs' motion to compel, defendant Lumenis has filed the declarations of Omer Peled and Robert Mann (Docket Entry Nos. 27 and 28). Mr. Peled is the Global Director of Intellectual Property for Lumenis and Mr. Mann is the Senior Vice President and General Manager of Lumenis Inc.'s Aesthetic Business. In these two declarations, Mr. Peled and Mr. Mann state that plaintiffs' arguments about the origins and design purposes of both the M22 device and the DUET device are incorrect. Specifically, neither of these devices were developed as an intended replacement for the Lumenis One, nor were they designed to "eliminate known

problems with the Lumenis One," as plaintiffs claim. According to the declarations of Mr. Peled and Mr. Mann, these three Lumenis devices serve different purposes in Lumenis's product line "and are geared toward different end users." (Docket Entry No. 28). According to these two declarations, the M22 and DUET products are materially different from the Lumenis One, including but not limited to their use of different software programs.

Based upon the record before the Court, the undersigned Magistrate Judge finds that the Lumenis M22 device and the Lumenis DUET device are materially dissimilar to the Lumenis One, and, therefore, that their designs are not relevant to the issues raised in this case. In addition, the undersigned Magistrate Judge finds that the information contained in the declarations of Mr. Peled and Mr. Mann constitute a sufficient response to interrogatories No. 12 and 13 such that a motion to compel further response must be denied.

Interrogatory No. 15 and Request for Production No. 15: Please describe any data, including Clinical Data, information, reports, or other documents provided to the Food and Drug Administration prior to marketing and selling the Lumenis One in the United States and specifically any information regarding the switching module and software control for the switching module.

Response No. 15: Objection. This interrogatory is overly broad and unduly burdensome. This interrogatory seeks information that is irrelevant and unlikely to lead to the discovery of admissible evidence. It seeks information that is confidential, proprietary, and/or trade secret. Notwithstanding and subject to these objections, Lumenis responds as follows:  
See response to Request for Production No. 15.

Supplemental Response No. 15: The Lumenis One received FDA approval based on its similarity to the predicate devices, which included the Lumenis Family of Intense Pulsed Light and IPL/Nd:Yag Systems, the LightSheer Pulsed Diode Array Laser System, and the Aluma Skin Renewal System.

As the above response states, defendant Lumenis has objected to producing all information provided to the Food and Drug Administration in connection with its premarket notification for the Lumenis One on grounds of relevance and the confidential and proprietary nature of the information. Based upon the allegations in the complaint, the undersigned Magistrate Judge finds that the request, which seeks "any data" provided to the FDA prior to marketing the Lumenis One to be excessive and unduly broad. For example, plaintiff's request would include all technical data relating to the effectiveness of the laser and light therapy elements of this machine, although these components are not challenged or questioned in the complaint. From a reading of the complaint, and from the documents supporting plaintiffs' motion to compel, it appears that plaintiffs are primarily interested in information relating to the switching module and software control for the switching module and the Rossi Patient Database included as components on the Lumenis One device. It further appears that plaintiffs suspect, at least preliminarily, that the excessive error messages and interruptions of patient treatment alleged in the complaint may be related to these components of the Lumenis One.

The undersigned Magistrate Judge finds that a request seeking "all data" supplied to the FDA is overly broad and unduly burdensome and, considering the highly proprietary and confidential nature of such data, the undersigned Magistrate Judge finds that plaintiffs' motion to compel response to the interrogatory and request for production as written must be denied.

Plaintiffs have combined their motion for leave to file a reply in support of their motion to compel with a motion for leave to amend their complaint, "if necessary" (Docket Entry No. 30). the Court previously granted that motion to the extent of leave to file a reply (Docket Entry No. 33).

Rule 15(a) of the Federal Rules of Civil Procedure provides that the court "should freely give leave [to amend pleadings] when justice so requires." Although plaintiffs seek leave to amend their complaint "if necessary," they have not filed a copy of the amendments they propose. Therefore, in the absence of a statement of the amendments that plaintiffs seek to make, the undersigned Magistrate Judge lacks any basis to determine whether "justice so requires." Therefore, the Court **DENIES** plaintiffs' motion for leave to amend their complaint without prejudice to their filing a properly supported motion.

Finally, plaintiffs have filed a motion for hearing on their motion to file reply in support of their motion to compel and to amend the complaint, if necessary (Docket Entry No. 31). In

view of the extensive briefing on these motions, the Court finds that a hearing would not be helpful in resolving these matters. Therefore, plaintiffs' motion for a hearing is **DENIED**.

Summarizing, the Court:

1. **grants** in part and **denies** in part plaintiffs' motion to compel (Docket Entry No. 24). The Court **grants** plaintiffs' motion and **orders** defendant Lumenis to produce, on or before **February 25, 2011**, any reports, complaints or notices from consumers, customers, governmental agencies or other sources related to excessive error messages, system shutdowns or other interruptions in patient treatment on the Lumenis One device, whether attributable to software problems, switching modules, or other causes. The Court otherwise **denies** plaintiffs' motion to compel;

2. Plaintiffs' motion for leave to amend the complaint, "if necessary," (Docket Entry No. 30) is **denied** without prejudice to plaintiffs' right to file a motion for leave to amend with proper support; and

3. Plaintiffs' motion for hearing (Docket Entry No. 31) is **denied**.

It is so **ORDERED**.

s/ John S. Bryant  
JOHN S. BRYANT  
United States Magistrate Judge